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FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER	
HINES, JANA A	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/325,095
Filing Date: June 03, 1999
Appellant(s): HILES ET AL.

Norman D. Hanson, Esq.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 22, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: The following rejections have been withdrawn:

The written description rejection of claims 51-58 and 60-61 under 35 U.S.C. 112, first paragraph;

The rejection of claims 51-58 and 60-61 under 35 U.S.C. 112, second paragraph for omitting essential steps; and

The indefiniteness rejection of claims 51-58 and 60-61 under 35 U.S.C. 112, second paragraph.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 51-58 and 60-61 do not stand or fall together, however the brief fails to set forth reasons why the claims stand or fall together as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51-58 and 60-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are drawn to a method for determining expression of a gene wherein the gene encodes a human polypeptide that has PI3 kinase activity and a molecular

weight of about 110 kD comprising contacting a sample with a nucleic acid molecule which hybridizes specifically to a transcript of said gene, wherein said transcript is RNA or cDNA, and selected from the group consisting of a) the nucleotide sequence set forth in SEQ ID NO: 32; b) the nucleotide sequence set forth in SEQ ID NO:35; and c) the nucleotide sequence which hybridizes to the complement of at least one of a) and b), at 1MNaCl, 10xDenhardt's solutions; 50mM Tris-HCl (pH 7.4); 10mM EDTA; 0.1% SDS; 100ug/ml denatured herring sperm DNA at 65°C for 16 hours, followed by a wash of 2XSSC; 0.1% SDS at 42°C, or a wash of 0.5XSSC/0.1% SDS at 50°C, or a wash at 0.1XSSC/0.1% SDS at 65°C, or a wash at 0.1XSSC/0.1% SDS at 68°C and determining said hybridization as a determination of expression of said gene.

There is no teaching within the specification for that appellants invention includes a method for the use of the polynucleotides disclosed therein for the purpose of determining expression of a gene wherein the gene encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD comprising contacting a sample with a nucleic acid molecule which hybridizes specifically to a transcript of said gene wherein said transcript is RNA or cDNA, and selected from the group consisting of a) the nucleotide sequence set forth in SEQ ID NO: 32; b) the nucleotide sequence set forth in SEQ ID NO:35; and c) the nucleotide sequence which hybridizes to the complement of at least one of a) and b), at the recited conditions and determining hybridization as a determination of expression of said gene.

There is no disclosure whatsoever that the nucleotide sequence of the invention could be used in a method for determining expression of a gene wherein the gene

encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD. There is no disclosure that the nucleotide sequences set forth in SEQ ID NO: 32 and SEQ ID NO:35 can be contacted with a sample comprising a nucleic acid molecule, said molecule specifically hybridizes to the sequences wherein said hybridization determines the expression of said gene. There is no disclosure that an undisclosed nucleotide sequence will hybridizes to the complement of at least SEQ ID NO:32 and SEQ ID NO:35, at the recited conditions and wherein said hybridization determines the expression of said gene. Moreover, there is no teaching in the specification that discloses the identity of the undisclosed nucleotide sequence as described in section c) which will hybridizes to the complement of at least SEQ ID NO:32 and SEQ ID NO:35, at the recited conditions to thereby determine gene expression. Finally, there is no disclosure that determining hybridization will also act as a determination of gene expression, which in-turn encodes a human polypeptide that has PI3 kinase activity, and has a molecular weight of about 110kD as determined by SDS-PAGE.

The specification teaches hybridization and Polymerase Chain Reaction (PCR) techniques at pages 39 and 41 of the instant specification, however there is no contemplation that such methods should be applied for determining expression of a gene wherein the gene encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD comprising the recited steps. Neither is the use of hybridization and PCR for the determination of gene expression implied in the teachings of the specification. The specification contemplates the use of these techniques in a

completely different context, such as for gene cloning. The hybridization process disclosed by the specification is a process whereby two complementary nucleic acid strands form a double helix during an annealing period thus allowing for the detection of specific nucleotide sequences. Therefore the detection of specific nucleotide sequences is not used with a method for determining gene expression. Moreover, the hybridization techniques fail to provide adequate support for an unrelated method drawn to determining gene expression. PCR allows for the DNA to be amplified a billion-fold thereby making numerous copies of the DNA. There is no contemplation that this amplification process is related to or used with a method for determining gene expression. Appellants' have failed to point to by page and line number for support of the instantly claimed method.

As to the dependant claims, SEQ ID NO: 15-19, 21-22, 24-25, 27 and 29 are disclosed as being primers, see pages 39-41 and are not disclosed as nucleic acid molecules which specifically hybridize to a transcript of the claimed gene, thus there is no support. Pages 38-39, 41-42 and 52-53 of the instant specification recites that SEQ ID NO: 15-19, 21-22, 24-25, 27 and 29 are useable as primers and not as radiolabelled oligonucleotides, detection reagents, or sequences useable in a method for determining gene expression. Moreover, it is noted that SEQ ID NO: 12 and 14 are disclosed by the specification as being detection reagents, see page 38 in experiments for cloning polypeptide p110 and not as oligonucleotide primers, as recited by claim 57. Therefore, there is no support for the recited claim limitations.

(11) Response to Argument

Response to Arguments Traversing the Rejection of Claims 51-58 and 60-61 Under 35 U.S.C. 112, first paragraph

In response to appellants' assertion that the claims do not incorporate new matter, it is noted that appellants' have failed to point to support in the specification for a method for determining expression of a gene wherein the gene encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD comprising a contact step wherein a nucleic acid molecule hybridizes specifically to a transcript of said gene and the determination of said hybridization determines the expression of said gene. It is further noted that even appellants' summary of invention section has failed to point to support within the specification for the claimed method. Moreover, there is no support for a method for determining expression of a gene wherein the gene encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD comprising contacting a sample with a nucleic acid molecule which hybridizes specifically to a transcript of said gene wherein said transcript is RNA or cDNA, and selected from the group consisting of a) the nucleotide sequence set forth in SEQ ID NO: 32; b) the nucleotide sequence set forth in SEQ ID NO:35; and c) the nucleotide sequence which hybridizes to the complement of at least one of a) and b), at 1MnaCl, 10xDenhardt's solutions; 50mM Tris-HCl (pH 7.4); 10mM EDTA; 0.1% SDS; 100ug/ml denatured herring sperm DNA at 65°C for 16 hours, followed by a wash of 2XSSC; 0.1% SDS at 42°C, or a wash of 0.5XSSC/0.1% SDS at 50°C, or a wash at 0.XSSC/0.1% SDS at 65°C, or a wash at 0.1XSSC/0.1% SDS at

68°C and determining said hybridization as a determination of expression of said gene within appellants' entire brief.

Appellants' assert that the examiner seems to confuse gene expression and protein expression. However, the issue of gene expression versus protein expression is irrelevant with respect to the issue of whether the claimed invention finds support in that application as filed. Appellants' are reminded that the issue is that the claimed subject matter is not disclosed in the original application therefore such claims have been rejected on the ground that they recite method steps without support in the original disclosure under 35 U.S.C. 112, first paragraph. See *Waldemar Link, GmbH & Co. v. Osteonics Corp.* 32 F.3d 556, 559, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994); *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). In this case, the new matter issue is drawn to the method for determining gene expression that was not disclosed in the original specification, claims, or drawings thus the claims are rejected accordingly. Appellants' assert that based on well known principles of molecular biology and that there is adequate support in the specification for determining gene expression from hybridization. However, there is no disclosure in the specification as filed that appellants' contemplate that their invention includes a method for determining expression of a gene wherein the gene encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD. Appellants have failed to point to support within the instant specification for a method of using the nucleotide sequences set forth in SEQ ID NO: 32 and SEQ ID NO:35 can be contacted with a sample comprising a nucleic acid molecule to determine the expression of said gene.

Appellant have failed to point to support that there is adequate support that an undisclosed nucleotide sequence will hybridizes to the complement of at least SEQ ID NO:32 and SEQ ID NO:35, at the recited conditions and wherein said hybridization determines the of expression of said gene. Appellants' have failed to point to by page and line number the support for a teaching in the specification that discloses the identity of the undisclosed nucleotide sequence as described in section c) which will hybridizes to the complement of at least SEQ ID NO:32 and SEQ ID NO:35, at the recited conditions to thereby determine gene expression. Finally, appellants' have failed to state where the specification provides an outline, a protocol, an experiments or even a working example for determining hybridization act as a determination of expression of a gene which encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110kD as determined by SDS-PAGE. Thus, in view of appellants' failure to point to support for the claimed method in the specification as filed, the rejection is proper.

Finally, appellants' assert that very high stringency conditions are recited. However this assertion is irrelevant with respect to the new matter rejection. The issue is not whether gene expression can be detected at the stringency conditions stated but rather that the specifications fails to contain a written description of using hybridization techniques for the purpose of determining gene expression. Thus, in view of appellants' failure to provide support, the rejection is maintained for the reasons stated above.

For the above reasons, it is believed that the new matter rejection should be sustained.

Respectfully submitted,

Ja-Na Hines
March 14, 2005

Conferee
Lynette Smith

Conferee
Paula Hutzell

Fulbright & Jaworski, L.L.P.
666 Fifth Avenue
New York, New York 10103